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UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER OF PATENTS AND TRADEMARKS Washington, D.C. 20231 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/960,749	09/21/2001	Thomas E. Borillo	593/005	5029
1473	7590 02/11/2003			
FISH & NEAVE			EXAMINER	
1251 AVENU 50TH FLOOR	E OF THE AMERICAS		BAXTER, I	ESSICA R
NEW YORK,	NY 10020-1105		ART UNIT	PAPER NUMBER
			3731	
			DATE MAILED: 02/11/2003	3

Please find below and/or attached an Office communication concerning this application or proceeding.

<del></del>							
		Application No.	Applicant(s)				
Office Action Summary		09/960,749	BORILLO ET AL.				
Office At	cuon Summary	Examiner	Art Unit				
		Jessica R Baxter	3731				
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply							
THE MAILING DAT  Extensions of time may be after SIX (6) MONTHS from the period for reply spector of the period for reply is spector of the period for reply received by the period for the per	E OF THIS COMMUNICATION.  e available under the provisions of 37 CFR 1.  m the mailing date of this communication.  iffied above is less than thirty (30) days, a rep-  pecified above, the maximum statutory period  set or extended period for reply will, by statute	Y IS SET TO EXPIRE 1 MONTH( 136(a). In no event, however, may a reply be time by within the statutory minimum of thirty (30) days will apply and will expire SIX (6) MONTHS from be, cause the application to become ABANDONEI g date of this communication, even if timely filed	nely filed s will be considered timely. the mailing date of this communication. D (35.U.S.C. & 133)				
1) Responsive t	o communication(s) filed on	<u>_</u> ·					
2a) ☐ This action is	FINAL. 2b) Th	nis action is non-final.					
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.  Disposition of Claims							
4)⊠ Claim(s) <u>1-38</u>	is/are pending in the application	1.					
4a) Of the abo	ve claim(s) is/are withdra	wn from consideration.					
5)							
6)							
	7) Claim(s) is/are objected to.						
	are subject to restriction and/or	election requirement					
Application Papers		orodion roquironioni.					
9) ☐ The specification	on is objected to by the Examine	r.					
10)☐ The drawing(s)	filed on is/are: a)□ acce	oted or b)⊡ objected to by the Exan	niner.				
		e drawing(s) be held in abeyance. Se					
		_ is: a) ☐ approved b) ☐ disappro					
If approved, corrected drawings are required in reply to this Office action.							
12)☐ The oath or declaration is objected to by the Examiner.							
Priority under 35 U.S.C	. §§ 119 and 120						
13) Acknowledgme	ent is made of a claim for foreigr	n priority under 35 U.S.C. § 119(a)	)-(d) or (f).				
	ome * c) None of:		., .,				
1.☐ Certified	copies of the priority document	s have been received.					
		s have been received in Application	on No.				
3.☐ Copies o appl	of the certified copies of the prior ecation from the International Bu	rity documents have been receive	d in this National Stage				
		•		`			
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  a) The translation of the foreign language provisional application has been received.							
15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.							
Attachment(s)							
Notice of References Cit     Notice of Draftsperson's     Information Disclosure S	ed (PTO-892) Patent Drawing Review (PTO-948) tatement(s) (PTO-1449) Paper No(s)	5) Notice of Informal Page	(PTO-413) Paper No(s) atent Application (PTO-152)				
S. Patent and Trademark Office							

#### **DETAILED ACTION**

#### Election/Restrictions

- 1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-8, drawn to catherization apparatus, classified in class 606, subclass 191.
  - II. Claims 9-16, drawn to method for establishing a transseptal conduit, classified in class 606, subclass 194.
  - III. Claims 17-27, drawn to a catherization apparatus, classified in class 604, subclass 96.01.
  - IV. Claims 28-38, drawn to a method for implanting a device in an atrium's appendage, classified in class 604, subclass 104.

The inventions are distinct, each from the other because of the following reasons:

- 2. Inventions I and III are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the position guide is not included in the combination. The subcombination has separate utility such as a catherization apparatus for use in implanting a device.
- 3. Inventions II and I are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice

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another and materially different process. (MPEP § 806.05(e)). In this case the process as claimed can be practiced by another materially different apparatus such as a catheter with puncturing means.

- 4. Inventions I and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not capable of use together since IV includes a method for using an apparatus of a different embodiment than the claimed invention.
- 5. Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are not capable of use together since II includes a method for using a different embodiment of the apparatus.
- 6. Inventions II and IV are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because it does not require the use of a positioning guide. The subcombination has separate utility such as a method for implanting a device in the atrium's appendage.
- 7. Inventions IV and III are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice

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another and materially different process. (MPEP § 806.05(e)). In this case the apparatus as claimed can be used practice the delivery of a device to any bodily opening.

- 8. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.
- 9. A telephone call was made to Manu Tejwani on February 6, 2003 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

10. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica R Baxter whose telephone number is 703-305-4069. The examiner can normally be reached on M-F 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on 703-308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-305-3590 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Jessica R Baxter Examiner Art Unit 3731

February 8, 2003

MICHAEL J. MILANO
SUPERVISORY PATENT EXAMINER

TECHNOLOGY CENTER 3700

# (MPEP Section 800 and Form Paragraph Section 8)

### Fill in 1-6 before calling

1. Attorney/Agent Name: Namu le	ω <u>α</u>		
2 Attorney Telephone Number: 217	591a - 9000		
3. Applicant Name: Borillo Thomas 4. Application Number: 09/9100749 5. Attorney Docket Number: 593/0	Sutton, Greggy		
4. Application Number: 09 9100749	, 00		
5. Attorney Docket Number. 593/c	<u> </u>		
6. This is			
an Election of Species:	Generic claims are		
•	Species I description		
(ask which claims are readable	Species II descriptionSpecies III description		
to the elected species)			
to the clotted species,			
a Restriction of Groups	Group I claims are 1-8 catherization apparatus		
	Group II claims are 9-16 method for establishing tro		
<u>.</u> .	Group III claims are 7-27 Cathour 200000		
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9. Generic claims with traverse _	without traverse		
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